

DECLARATION OF EMERGENCY

Department of Health and Hospitals Bureau of Health Services Financing

Abortion Facilities
Licensing Standards
(LAC 48:I.Chapter 44)

The Department of Health and Hospitals, Bureau of Health Services Financing repeals and replaces LAC 48:I.Chapter 44 in the Medical Assistance Program as authorized by R.S. 36:254 and R.S. 40:2175.1 et seq. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Bureau of Health Services Financing amended the provisions governing the licensing of abortion facilities in order to clarify the licensing requirements and staffing provisions (*Louisiana Register*, Volume 39, Number 8).

Acts 259 and 260 of the 2013 Regular Session of the Louisiana Legislature amended the laws governing abortion services and the Louisiana Children's Code. The department now proposes to repeal and replace the licensing standards governing outpatient abortion facilities in order to revise and clarify these provisions, and to comply with the provisions of Acts 259 and 260.

This action is being taken to promote the health and welfare of Louisiana citizens by assuring the health and safety of women seeking health care services at licensed abortion facilities. It is estimated that implementation of this Emergency Rule will have no programmatic costs for state fiscal year 2013-2014.

Effective November 20, 2013, the Department of Health and Hospitals, Bureau of Health Services Financing repeals and replaces the provisions governing the licensing standards for abortion facilities.

Title 48

PUBLIC HEALTH—GENERAL

Part I. General Administration

Subpart 3. Licensing and Certification

Chapter 44. Abortion Facilities

Subchapter A. General Provisions

§4401. Definitions

Abortion—any surgical procedure performed, after pregnancy has been medically verified, with the intent to cause the termination of the pregnancy other than for the purpose of:

1. producing a live birth;
2. removing an ectopic pregnancy; or
3. removing a dead fetus caused by a spontaneous abortion.

Administrator—the person responsible for the day-to-day management, supervision, and operation of the outpatient abortion facility.

Change of Ownership (CHOW)—transfer of ownership to someone other than the owner listed on the initial licensing application or license renewal application.

CRNA—a certified registered nurse anesthetist licensed by the Louisiana State Board of Nursing who is under the supervision of the physician performing the abortion or an anesthesiologist who is immediately available if needed as defined in the medical staff bylaws and in accordance with applicable licensing boards.

Department—the Department of Health and Hospitals (DHH).

First Trimester—the time period from 6 to 14 weeks after the first day of the last menstrual period.

General Anesthesia—any drug, element, or other material which, when administered, results in a controlled state of unconsciousness accompanied by a partial or complete loss of protective reflexes, including a loss of ability to independently maintain an airway and respond purposefully to physical stimuli or verbal command.

Gestational Age—the age of the unborn child as measured by the time elapsed since the first day of the last menstrual period as determined by a physician and confirmed through the use of an ultrasound.

HSS—the Department of Health and Hospitals, Health Standards Section.

Medical Director—a physician who is responsible for all of the medical care provided to patients in the outpatient abortion facility, and for the ethical and professional practices of the medical staff.

OPH—the Department of Health and Hospitals, Office of Public Health.

OSFM—the Department of Public Safety and Corrections, Office of State Fire Marshal, Public Safety Services.

Outpatient Abortion Facility—any outpatient facility or clinic, other than a hospital as defined in R.S. 40:2102 or an ambulatory surgical center as defined in R.S. 40:2133, in which any second trimester or five or more first trimester abortions are performed per month.

Patient—the woman receiving services from an outpatient abortion facility.

Physician—a doctor who possesses a current license to practice medicine in Louisiana, is in good standing with the Louisiana State Board of Medical Examiners, and whose license does not restrict the doctor from performing the services at the outpatient abortion facility.

Products of Conception—placenta, amniotic sac or membrane, embryo, or fetal elements that result from a human pregnancy.

Second Trimester—the time period from 14 to 23 weeks after the first day of the last menstrual period.

Secretary—the secretary of the Louisiana Department of Health and Hospitals.

Serious Harm—an incident which involves:

1. unconsciousness;
2. physical pain evidenced by objective findings;
3. disfigurement;
4. loss or impairment of the function of a body member, organ, or mental faculty; or
5. severe emotional distress.

Telecommunications—any means of transmitting messages at a distance, including but not limited to:

1. telephones;
2. cell phones;
3. pagers; or
4. other similar devices which foster communication.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4403. General Licensing Provisions

A. It shall be unlawful for outpatient abortion facilities in the initial licensing application process to accept patients or provide abortion services until licensed by the Department of Health and Hospitals (DHH). The department is the only licensing authority for outpatient abortion facilities in Louisiana.

B. Types of Licenses. The department shall have the authority to issue the following types of licenses:

1. full initial license;
2. provisional initial license;
3. full renewal license; and
4. provisional renewal license.

C. An outpatient abortion facility shall be in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to an abortion or abortion procedures before the outpatient abortion facility will be issued an initial license to operate.

D. An outpatient abortion facility license shall:

1. be issued only to the person or entity named in the initial licensing application;
2. be valid only for the outpatient abortion facility to which it is issued and only for the physical address named in the initial licensing application;
3. be valid for one year from the date of issuance, unless revoked or suspended, prior to that date, or unless a provisional initial license or provisional renewal license is issued;
4. expire on the last day of the twelfth month after the date of issuance, unless timely renewed by the outpatient abortion facility;
5. not be subject to sale, assignment, donation, or other transfer, whether voluntary or involuntary; and
6. be posted in a conspicuous place on the licensed premises at all times.

E. An outpatient abortion facility licensed by the department may only perform first and second trimester abortions, unless otherwise provided by law.

F. A separately licensed outpatient abortion facility shall not use a name which is substantially the same as the name of another such facility licensed by the department. An outpatient abortion facility shall not use a name which is likely to mislead the patient or their family into believing it is owned, endorsed, or operated by the state of Louisiana.

G. No branches, satellite locations, or offsite campuses shall be authorized for an outpatient abortion facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4405. Initial Licensing Application Process

A. The initial licensing application process includes submission and approval of plans and specifications (construction documents) and an initial licensing application packet, including but not limited to, a facility need review approval letter. No outpatient abortion facility shall accept patients or provide abortion services until in compliance with the provisions of this Chapter.

B. Plan Review Approval. All plans and specifications (construction documents) submitted by or on behalf of the outpatient abortion facility are required to be submitted and approved by the Office of State Fire Marshal (OSFM) as part of the licensing application process.

1. Applicants are required to refer to the OSFM for laws, rules, and editions of adopted codes and standards applicable to plan review by the OSFM.

2. One complete set of plans and specifications (construction documents) with application and review fee shall be submitted to the OSFM for review.

3. Plan review submittal to the OSFM shall be in accordance with R.S. 40:1574, LAC 55:V, Chapter 3, and the following.

a. Modifications to Physical Environment. Any proposed change to the physical environment shall require review for compliance with requirements applicable at the time of the proposed change. Normal maintenance, reroofing, and painting do not require plan review by the OSFM.

b. The specific requirements outlined in the physical environment Section of this Chapter.

c. Where services or treatment for four or more patients is provided, requirements applicable to ambulatory health care occupancies, as defined by the most recently state adopted edition of National Fire Protection Association (NFPA) 101, shall apply.

d. Where services or treatment for three or less patients is provided, requirements applicable to construction of business occupancies, as defined by the most recently state adopted edition of NFPA 101, shall apply.

4. Upon approval, one copy of the documents reviewed by the OSFM and one copy of the OSFM plan review letter shall be submitted to the department. Electronic transfer of documents by the OSFM to the department is allowed to satisfy this requirement.

5. Waivers. When a requirement of these rules regarding plan review would impose a hardship, financial or otherwise, but would not adversely affect the health and safety of any patient, the outpatient abortion facility may submit a waiver request to the department, with supporting documentation. The issuance of a waiver by the department does not apply to the OSFM requirements for approval, which must be addressed exclusively by the outpatient abortion facility with the OSFM or the state health officer, as appropriate to the subject matter.

C. Initial Licensing Application Packet. An initial licensing application packet for an outpatient abortion facility shall be obtained from the department. A complete initial licensing application packet shall be submitted to and approved by the department prior to an applicant providing abortion services as an outpatient abortion facility.

D. To be considered complete, the initial licensing application packet shall include the following:

1. a completed outpatient abortion facility initial licensing application and the non-refundable initial licensing fee;

2. a copy of the approval letter of the architectural facility plans for the outpatient abortion facility by the OSFM;

3. a copy of the on-site inspection report with approval for occupancy from the OSFM;

4. a copy of the health inspection report from the Office of Public Health (OPH);

5. an organizational chart identifying the name, position, and title of each person composing the governing body and key administrative personnel;

6. a floor sketch or drawing of the premises to be licensed;

7. a copy of the facility need review approval letter; and

8. any other documentation or information required by department for licensure.

E. If the initial licensing application packet is incomplete as submitted, the applicant shall be notified in writing of the missing information and shall have 90 calendar days from receipt of the notification to submit the additional requested information. If the additional requested information is not timely submitted to the department within 90 calendar days, the initial licensing application shall be closed. If an initial licensing application is closed, an applicant who is still interested in operating an outpatient abortion facility must submit a newly completed initial licensing application packet and a new non-refundable initial licensing fee to begin the initial licensing application process again, subject to any facility need review approval.

F. Initial Licensing Surveys. Upon receipt of a complete initial licensing application packet, the department shall conduct an on-site initial licensing survey prior to issuing a full initial license. The initial licensing survey shall be announced.

1. If it is determined that the applicant is not in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures, and a potential threat to the health, safety, and welfare of the patients is presented, the department shall deny the initial licensing application.

2. If it is determined that the applicant is in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures, the department shall issue a full initial license to the applicant.

G. Full Initial License. The full initial license issued by the department shall be valid until the expiration date shown on the license unless the license is revoked or suspended prior to that date.

1. If it is determined that the applicant is not in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures, but the department, in its sole discretion determines that the noncompliance does not present a threat to the health, safety, and welfare of the patients, the department may issue a provisional initial license.

H. Provisional Initial License. The provisional initial license issued by the department shall be valid for a period not to exceed six months.

1. When a provisional initial license is issued by the department, the applicant shall submit a plan of correction to the department for approval and also shall be required to correct all deficiencies prior to the expiration of the provisional initial license.

2. Upon receipt of the applicant's plan of correction, the department shall conduct an unannounced follow-up survey, either on-site or by desk review, to ensure the applicant is in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures.

- a. Following the follow-up survey, if it is determined that the applicant has corrected all deficiencies and has maintained compliance during the period of the provisional license, the department shall issue a full initial license for the remainder of the year.

- b. Following the follow-up survey, if it is determined that the applicant has failed to correct all deficiencies, the provisional initial license shall expire unless otherwise determined by the department. The applicant shall be required to submit a newly completed initial licensing application packet and a new non-refundable initial licensing fee to begin the initial licensing application process again subject to any facility need review approval.

- I. Informal Reconsideration and Administrative Appeal. The outpatient abortion facility does not have the right to request an informal reconsideration and/or an administrative appeal of the issuance of a provisional initial license. An outpatient abortion facility that has been issued a provisional initial license is considered licensed and operational for the term of the provisional initial license. The issuance of a provisional initial license is not considered to be a denial of an initial licensing application, denial of a license renewal application, or license revocation for the purposes of this Chapter.

J. Informal Reconsideration. An outpatient abortion facility that has been issued a provisional initial license has the right to request an informal reconsideration regarding the validity of the deficiencies cited during the follow-up survey.

1. The request for an informal reconsideration must be in writing and received by HSS within five days of receipt of the statement of deficiencies. If a timely request for an informal reconsideration is received, HSS shall schedule the informal reconsideration and notify the outpatient abortion facility in writing.

2. The request for an informal reconsideration must identify each disputed deficiency or deficiencies and the reason for the dispute and include any documentation that demonstrates that the determination was made in error.

3. Correction of a deficiency or deficiencies cited in a follow-up survey shall not be the basis for an informal reconsideration.

K. Administrative Appeal. An outpatient abortion facility that has been issued a provisional initial license has the right to request an administrative appeal regarding the validity of the deficiencies cited during the follow-up survey.

1. The request for an administrative appeal must be in writing and received by the Division of Administrative Law (DAL), or its successor, within 15 days of receipt of the statement of deficiencies.

2. The request for an administrative appeal must identify each disputed deficiency or deficiencies and the reason for the dispute and include any documentation that demonstrates that the determination was made in error.

3. Correction of a deficiency or deficiencies cited in a follow-up survey shall not be the basis for an administrative appeal.

4. Upon expiration of the provisional initial license, the outpatient abortion facility shall immediately cease and desist providing abortion services unless the DAL, or its successor, issues a stay of the expiration.

5. Stay of the Expiration. The request for a stay of the expiration must be submitted with the request for an administrative appeal and received by the DAL, or its successor, within 15 days of receipt of the statement of deficiencies.

a. Following a contradictory hearing and only upon a showing that there is no potential harm to the patients being served by the outpatient abortion facility, the stay may be granted by the DAL, or its successor.

6. If a timely request for an administrative appeal is received, the DAL, or its successor, shall conduct the administrative appeal within 90 calendar days of the docketing of the administrative appeal. For good cause shown, the DAL, or its successor, may grant one extension, not to exceed 90 calendar days.

a. If the final decision of the DAL, or its successor, is to remove all deficiencies, the outpatient abortion facility's license shall be granted/re-instated upon the payment of any licensing fees, outstanding sanctions, or other fees due to the department.

b. If the final decision of the DAL, or its successor, is to uphold the deficiencies and affirm the expiration of the provisional initial license, the outpatient abortion facility shall:

i. immediately cease and desist providing abortion services as an outpatient abortion facility;

ii. return the outpatient abortion facility license to the department; and

iii. notify the department in writing of the secure and confidential location where the patient medical records will be stored, including the name, physical address, and contact person, within 10 days of the rendering of the administrative appeal judgment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4407. Survey Activities

A. Any applicant or outpatient abortion facility shall be subject to licensing surveys conducted by department surveyors to ensure that an applicant or outpatient abortion facility is in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures, and also to ensure there is no present threat to the health, safety, and welfare of the patient.

B. Any applicant or outpatient abortion facility subject to licensing surveys conducted by the department shall:

1. allow department surveyors access to any and all requested documents and information on the licensed premises, including, but not limited to, patient medical records and outpatient abortion facility records;

2. allow department surveyors access to interview any staff or other persons as necessary or required; and

3. not interfere or impede the survey process for department surveyors while conducting any survey.

C. The department is entitled to access all books, records, or other documents maintained by or on behalf of the outpatient abortion facility on the licensed premises to the extent necessary to ensure compliance with this Chapter. Ensuring compliance includes permitting photocopying by the department or providing photocopies to the department of any records or other information by or on behalf of the outpatient abortion facility as necessary to determine or verify compliance with this Chapter.

D. Types of Surveys. The department shall have the authority to conduct the following types of surveys.

1. Initial Licensing Surveys. The department shall conduct an on-site initial licensing survey to ensure the applicant is in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures prior to issuing a full initial license. All initial licensing surveys shall be announced.

2. Annual Licensing Surveys. The department shall conduct an annual licensing survey. All annual licensing surveys shall be unannounced.

3. Complaint Surveys. The department shall conduct complaint surveys when a complaint is lodged against an outpatient abortion facility in accordance with R.S. 40:2009.13 et seq. All complaint surveys shall be unannounced.

4. Follow-up Surveys. The department may conduct a follow-up survey to ensure the outpatient abortion facility has corrected all deficiencies cited in the previous survey and is in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures. All follow-up surveys shall be unannounced.

E. Statement of Deficiencies. Following any survey, the department surveyors shall complete the statement of deficiencies documenting relevant findings including the deficiency, the applicable governing rule, and the evidence supporting why the rule was not met including, but not limited to, observations, interviews, and record review of information obtained during the survey. The outpatient abortion facility shall receive a copy of the statement of deficiencies.

1. Display. The following statements of deficiencies issued by the department to the outpatient abortion facility must be posted in a conspicuous place on the licensed premises:

- a. the most recent annual licensing survey statement of deficiencies; and
- b. any follow-up and/or complaint survey statement of deficiencies issued after the most recent annual licensing survey.

2. Public Disclosure. Any statement of deficiencies issued by the department to an outpatient abortion facility shall be available for disclosure to the public within 30 calendar days after the outpatient abortion facility submits an acceptable plan of correction to the deficiencies or within 90 days of receipt of the statement of deficiencies, whichever occurs first.

F. Plan of Correction. The department may require a plan of correction from an outpatient abortion facility following any survey wherein deficiencies have been cited. The fact that a plan of correction is accepted by the department does not preclude the department from pursuing other actions against the outpatient abortion facility as a result of the cited deficiencies.

G. Informal Reconsideration. The applicant and/or outpatient abortion facility shall have the right to request an informal reconsideration of any deficiencies cited during any initial licensing survey, annual licensing survey, and follow-up survey.

1. The request for an informal reconsideration must be in writing and received by HSS within 10 calendar days of receipt of the statement of deficiencies. If a timely request for an informal reconsideration is received, HSS shall schedule the informal reconsideration and notify the outpatient abortion facility in writing.

2. The request for an informal reconsideration must identify each disputed deficiency or deficiencies and the reason for the dispute and include any documentation that demonstrates that the determination was made in error.

3. Correction of the deficiency or deficiencies cited in any survey shall not be the basis for an informal reconsideration.

4. The outpatient abortion facility may appear in person at the informal reconsideration and may be represented by counsel.

5. The outpatient abortion facility shall receive written notice of the results of the informal reconsideration.

6. The results of the informal reconsideration shall be the final administrative decision regarding the deficiencies and no right to an administrative appeal shall be available.

H. Complaint Survey Informal Reconsideration. Pursuant to R.S. 40:2009.13 et seq., an outpatient abortion facility shall have the right to request an informal reconsideration of the validity of the deficiencies cited during any complaint survey and the complainant shall be afforded the opportunity to request an informal reconsideration of the findings.

1. The department shall conduct the informal reconsideration by desk review.

2. The outpatient abortion facility and the complainant shall receive written notice of the results of the informal reconsideration.

3. Except for the right to an administrative appeal provided in R.S. 40:2009.16(A), the results of the informal reconsideration shall be the final administrative decision and no right to an administrative appeal shall be available.

I. Complaint Survey Administrative Appeal. Pursuant to R.S. 40:2009.16, the outpatient abortion facility and the complainant have the right to request an administrative appeal on a complaint in which the department determines that the complaint concerns a patient in a facility and involves issues that have resulted or are likely to result in serious harm or death to a patient.

J. Sanctions. The department may impose sanctions as a result of deficiencies cited following any survey. A sanction may include, but is not limited to:

1. civil fine(s);
2. a plan of correction;
3. revocation of license;
4. denial of license renewal application;
5. immediate suspension of license; and
6. any and all sanctions allowed under federal or state law or regulation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4409. Changes in Outpatient Abortion Facility Information or Key Administrative Personnel

A. An outpatient abortion facility license shall be valid for the person or entity named as the outpatient abortion facility and for the physical address provided by the applicant on the initial licensing application or by the outpatient abortion facility in the licensing renewal application submitted to the department.

B. Change of Information. Any change regarding the outpatient abortion facility's entity name, "doing business as" name, mailing address, telephone number, or any combination thereof, shall be reported in writing to the department within five calendar days of the change. Any change regarding the entity name or "doing business as" name requires a change to the outpatient abortion facility license and shall require a \$25 fee for the issuance of an amended license.

C. Change of Key Administrative Personnel. Any change regarding the outpatient abortion facility's key administrative personnel shall be reported in writing to the department within five calendar days of the change. For the purposes of this Chapter, key administrative personnel includes the administrator and medical director, and the outpatient abortion facility shall provide the individual's name, hire date, and qualifications as defined in this Chapter.

D. Change of Ownership. A change of ownership (CHOW) of an outpatient abortion facility shall be reported in writing to the department at least five calendar days prior to the change. Within five calendar days following the change, the new owner shall submit to HSS all legal documents relating to the CHOW, an initial licensing application packet, and the non-refundable initial licensing fee. Once all required documentation and information is submitted and complete, HSS will review. If the CHOW is approved, the department shall issue a new license in the name of the new owner.

1. If the department has issued a notice of license revocation or a notice of immediate suspension at the time the CHOW is submitted, the department shall deny the CHOW.

E. Change of Physical Address. An outpatient abortion facility that intends to change the physical address is required to obtain plan review approval from the OSFM in accordance with the provisions of this Chapter.

1. Because the license of an outpatient abortion facility is not transferrable or assignable, any proposed change in the physical address requires the outpatient abortion facility to submit a newly completed initial licensing application packet and a new non-refundable initial licensing fee. In addition, the outpatient abortion facility must submit a written notice of intent to relocate to the HSS at the time the plan review request is submitted to the OSFM for approval.

2. The department shall conduct an announced on-site survey at the proposed new location prior to relocation of the facility.

3. Any change regarding the outpatient abortion facility's physical address shall result in a new anniversary date for the license issued.

F. Duplicate License. Any request for a duplicate license shall be accompanied by a \$25 fee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4411. License Renewal Application Process

A. License Renewal Application Packet. A license renewal application packet for an outpatient abortion facility shall be obtained from the department. A complete license

renewal application packet shall be submitted to the department at least 30 calendar days prior to the expiration of the current license.

B. To be considered complete, the license renewal application packet shall include the following:

1. a completed outpatient abortion facility license renewal application and the non-refundable license renewal fee;

2. a copy of the most current on-site inspection report with approval for occupancy from the OSFM;

3. a copy of the most current health inspection report with approval for occupancy from the OPH; and

4. any other documentation required by the department for licensure.

C. If the license renewal application packet is incomplete as submitted, the outpatient abortion facility shall be notified in writing of the missing information, and shall have 10 calendar days from receipt of the notification to submit the additional requested information. If the additional requested information is not received prior to the expiration of the current license, it will result in the voluntary non-renewal of the outpatient abortion facility license.

D. Annual Licensing Survey. Upon receipt of a complete license renewal application packet, the department may conduct an on-site annual licensing survey. This annual licensing survey shall be unannounced.

1. If it is determined that the outpatient abortion facility is not in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures, and that a potential threat to the health, safety, and welfare of the patients is presented, the department shall deny the license renewal application.

2. If it is determined that the outpatient abortion facility is in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures, the department shall issue a full renewal license to the outpatient abortion facility.

E. Full Renewal License. The full renewal license issued by the department shall be valid until the expiration date shown on the license, unless the license is modified, revoked, or suspended.

1. If it is determined that the outpatient abortion facility is not in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures, but the department, in its sole discretion, determines that the noncompliance does not present a threat to the health, safety,

and welfare of the patients, the department may issue a provisional renewal license.

F. **Provisional Renewal License.** The provisional renewal license issued by the department shall be valid for a period not to exceed six months.

1. At the discretion of the department, the provisional renewal license may be extended for an additional period not to exceed 90 calendar days in order for the outpatient abortion facility to correct the deficiencies cited following any survey.

2. When a provisional renewal license is issued by the department, the outpatient abortion facility shall submit a plan of correction to the department for approval and also shall be required to correct all deficiencies prior to the expiration of the provisional renewal license.

3. Upon receipt of the outpatient abortion facility's plan of correction, the department shall conduct an unannounced follow-up survey, either on-site or by desk review, to ensure the outpatient abortion facility is in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures.

a. Following the follow-up survey, if it is determined that the outpatient abortion facility has corrected all deficiencies and has maintained compliance during the period of the provisional license, the department may issue a full renewal license for the remainder of the year until the anniversary date of the issuance of the outpatient abortion facility license.

b. Following the follow-up survey, if it is determined that the outpatient abortion facility has failed to correct all deficiencies or has not maintained compliance during the period of the provisional renewal license, or if new deficiencies are cited during the follow-up survey that present a threat to the health, safety, and welfare of a patient, the provisional renewal license shall expire unless otherwise determined by the department. The outpatient abortion facility shall submit a newly completed initial licensing application packet and a new non-refundable initial licensing fee to begin the initial licensing application process again, subject to any facility need review approval.

G. The issuance of a full renewal license does not in any manner affect any previously existing sanction by the department against the outpatient abortion facility including, but not limited to, a civil fine(s), plan of correction, revocation of license, or immediate suspension of license.

H. If the department has issued a notice of license revocation or notice of immediate suspension of license at the time the license renewal application packet is submitted, the department shall deny the license renewal application.

I. **Informal Reconsideration and Administrative Appeal.** The outpatient abortion facility does not have the right to request an informal reconsideration and/or an administrative appeal of the issuance of a provisional renewal license. An outpatient abortion facility that has been issued a provisional renewal license is considered licensed and operational for

the term of the initial renewal provisional license. The issuance of a provisional renewal license is not considered to be a denial of an initial licensing application, denial of a license renewal application, or license revocation for the purposes of this Chapter.

J. **Informal Reconsideration.** An outpatient abortion facility that has been issued a provisional renewal license has the right to request an informal reconsideration regarding the validity of the deficiencies cited during the follow-up survey.

1. The request for an informal reconsideration must be in writing and received by HSS within five days of receipt of the statement of deficiencies. If a timely request for an informal reconsideration is received, HSS shall schedule the informal reconsideration and notify the outpatient abortion facility in writing.

2. The request for an informal reconsideration must identify each disputed deficiency or deficiencies and the reason for the dispute and include any documentation that demonstrates that the determination was made in error.

3. Correction of a deficiency or deficiencies cited in a follow-up survey shall not be the basis for an informal reconsideration.

K. **Administrative Appeal.** An outpatient abortion facility that has been issued a provisional renewal license has the right to request an administrative appeal regarding the validity of the deficiencies cited during the follow-up survey.

1. The request for an administrative appeal must be in writing and received by the DAL, or its successor, within 15 days of receipt of the statement of deficiencies.

2. The request for an administrative appeal must identify each disputed deficiency or deficiencies and the reason for the dispute and include any documentation that demonstrates that the determination was made in error.

3. Correction of a deficiency or deficiencies cited in a follow-up survey shall not be the basis for an administrative appeal.

4. Upon expiration of the provisional renewal license, the outpatient abortion facility shall immediately cease and desist providing abortion services unless the DAL, or its successor, issues a stay of the expiration.

5. **Stay of the Expiration.** The request for a stay of the expiration must be submitted with the request for an administrative appeal and received by the DAL, or its successor, within 15 days of receipt of the statement of deficiencies.

a. Following a contradictory hearing and only upon a showing that there is no potential harm to the patients being served by the outpatient abortion facility, the stay may be granted by the DAL, or its successor.

6. If a timely request for an administrative appeal is received, the DAL, or its successor, shall conduct the administrative appeal within 90 calendar days of the docketing of the administrative appeal. For good cause shown, the DAL, or its successor, may grant one extension, not to exceed 90 calendar days.

a. If the final decision of the DAL, or its successor, is to remove all deficiencies, the outpatient abortion facility's license will be granted/re-instated upon the payment of any licensing fees, outstanding sanctions, or other fees due to the department.

b. If the final decision of the DAL, or its successor, is to remove some but not all deficiencies, the department shall have the discretion to determine the operational status of the outpatient abortion facility.

c. If the final decision of the DAL, or its successor, is to uphold the deficiencies and affirm the expiration of the provisional renewal license, the outpatient abortion facility shall:

i. immediately cease and desist providing abortion services as an outpatient abortion facility;

ii. return the outpatient abortion facility license to the department; and

iii. notify the department in writing of the secure and confidential location where the patient medical records will be stored, including the name, physical address, and contact person, within 10 days of the rendering of the administrative appeal judgment.

L. Voluntary Non-Renewal of License

1. If an outpatient abortion facility fails to timely renew its license, the license shall expire on its face and is considered to be a voluntary non-renewal of license. At such time, the outpatient abortion facility shall immediately cease and desist providing abortions as an outpatient abortion facility.

2. Notice of Voluntary Non-Renewal of License. The outpatient abortion facility must provide advanced written notice of its voluntary non-renewal of license at least 30 calendar days prior to the date of the expiration of the outpatient abortion facility license. The notice of voluntary non-renewal of the license must be provided to all of the outpatient abortion facility's staff, including the medical director, to any patient having an abortion procedure within the last 30 calendar days of operation, and to HSS.

3. In addition, the outpatient abortion facility shall notify HSS in writing of the secure and confidential location where the patient medical records will be stored, including the name, physical address, and contact person.

4. As this is a voluntary action on the part of the outpatient abortion facility, no informal reconsideration or administrative appeal rights shall be available.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4413. Cessation of Business

A. Outpatient Abortion Facility Duties and Responsibilities. An outpatient abortion facility that intends to close or cease operations shall comply with the procedures of this Chapter.

1. Notice of Cessation of Business. The outpatient abortion facility must provide advanced written notice of its cessation of business at least 30 calendar days prior to the date it intends to cease business operations. The notice of cessation of business must be provided to all the outpatient abortion facility's staff, including the medical director, to any patient having an abortion procedure within the last 30 days of operation, and to HSS.

2. In addition, the outpatient abortion facility must notify HSS in writing of the secure and confidential location where the patient medical records will be stored, including the name, physical address, and contact person.

B. If an outpatient abortion facility fails to follow the procedures of this Chapter, any owner, officer, member, manager, director, or administrator of the outpatient abortion facility may be prohibited from owning, managing, directing, or operating another outpatient abortion facility in the state of Louisiana for two years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4415. Denial of an Initial License, Denial of License Renewal Application, and License Revocation

A. Denial of an Initial License

1. The department shall deny an initial license in the event that the initial licensing survey finds that the outpatient abortion facility is not in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures, and a potential threat to the health, safety, and welfare of the patients is presented.

2. The department shall deny an initial license for any of the reasons a license may be revoked or non-renewed pursuant to the provisions of this Chapter.

B. Denial of License Renewal Application and License Revocation. The department may deny a license renewal application or revoke a license for any of the following reasons:

1. failure to be in substantial compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures;

2. failure to comply with the terms and provisions of an education letter or settlement agreement;

3. failure to protect a patient from any act posing a threat to a patient's health and safety while on the licensed premises receiving services provided by the outpatient abortion facility;

4. knowingly providing false, forged, or altered statements or information on any documentation required to be submitted to the department or required to be maintained by the outpatient abortion facility, including, but not limited to:

a. the initial licensing application packet or the license renewal application packet;

b. data forms;

c. patient medical records or outpatient abortion facility records; or

d. matters under investigation by the department, the Office of the Attorney General, or law enforcement agencies;

5. knowingly making a false statement or providing false, forged, or altered information or documentation to DHH employees or to law enforcement agencies;

6. employing false, fraudulent, or misleading advertising practices;

7. an owner, officer, member, manager, administrator, director, managing employee, or person designated to manage or supervise patient care has either pled guilty or nolo contendere to a felony, or has been convicted of a felony, as documented by a certified copy of the record of the adjudicating court:

a. for purposes of these provisions, conviction of a felony means a felony relating to any of the following:

i. the violence, abuse, or neglect of a patient;
ii. cruelty, exploitation, or the sexual battery of a juvenile or the infirmed;

iii. a drug offense;

iv. crimes of a sexual nature;

v. possession, use of a firearm or deadly weapon;

or

vi. fraud or misappropriation of federal or state funds;

8. failure to comply with all reporting requirements in a timely manner, as required by all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures;

9. failure to allow the department surveyors access to any and all requested documents and information on the licensed premises, including, but not limited to, patient medical records and outpatient abortion facility records;

10. failure to allow the department surveyors access to interview any staff or other persons as necessary or required;

11. interfering or impeding with the survey process;

12. bribery, harassment, intimidation, or solicitation of any patient, by or on behalf of the outpatient abortion facility, designed to cause that patient to use or retain the services of the outpatient abortion facility;

13. failure to follow the cessation of business procedures as provided in this Chapter; or

14. failure to timely pay any licensing fees, outstanding sanctions, or other fees due to the department. For the purposes of this Chapter, any payments returned for insufficient funds are considered failure to timely pay.

C. Notice. The secretary shall provide 30 calendar days written notice of the denial of initial license, notice of denial of license renewal application, and notice of license revocation.

D. Informal Reconsideration. The applicant and/or outpatient abortion facility has the right to request an informal reconsideration of a decision by the department to deny an initial license, to deny a license renewal application, or to issue a revocation action of a license to operate an outpatient abortion facility. This informal reconsideration is limited to the reconsideration of the deficiencies or findings which make the basis for the license denial or revocation action and the results of this reconsideration are forwarded to the secretary for review and decision regarding the denial or revocation action. The applicant and/or outpatient

abortion facility will receive written notice of the final results and decision. However, there is no right to request an informal reconsideration of a voluntary non-renewal of license as provided in this Chapter.

1. The request for an informal reconsideration must be in writing and received by HSS within 15 calendar days of receipt of the notice of the denial of initial license, notice of denial of license renewal application, or notice of license revocation.

2. The request for an informal reconsideration shall include any documentation that demonstrates that the determination was made in error.

3. If a timely request for an informal reconsideration is received, HSS shall schedule the informal reconsideration and notify the applicant and/or outpatient abortion facility in writing.

4. The applicant and/or outpatient abortion facility shall have the right to appear in person at the informal reconsideration and may be represented by counsel.

5. Correction of a deficiency or deficiencies that is the basis for the denial of initial license, denial of license renewal application, or license revocation shall not be a basis for an informal reconsideration.

6. The informal reconsideration process is not in lieu of the administrative appeals process.

7. The applicant and/or outpatient abortion facility shall receive written notice of the results of the informal reconsideration.

E. Administrative Appeals. The applicant and/or outpatient abortion facility has the right to request a suspensive administrative appeal of the secretary's decision to deny an initial license, deny a license renewal application, or to revoke a license to operate an outpatient abortion facility. There is no right to request a suspensive administrative appeal of a voluntary non-renewal of license as provided in this Chapter.

1. The request for a suspensive administrative appeal must be in writing and received by the Office of the Secretary within 30 calendar days of receipt of the notice of the results of the informal reconsideration. A copy of the request for a suspensive administrative appeal shall be submitted to the DAL, or its successor.

a. Administrative Appeal Only. The applicant and/or outpatient abortion facility may forego its right to an informal reconsideration and proceed directly to a suspensive administrative appeal. In such a case, the request for a suspensive administrative appeal must be in writing and received by the Office of the Secretary within 30 calendar days of receipt of the notice of denial of initial licensing application, notice of denial of license renewal application, or notice of license revocation. The provisions of this Chapter shall otherwise govern this suspensive administrative appeal.

2. If a timely request for a suspensive administrative appeal is received, the Office of the Secretary shall forward the applicant and/or outpatient abortion facility's request and any accompanying documentation, to the DAL, or its successor, to be docketed, and send a copy of such request to the applicant or outpatient abortion facility either by U.S. mail, facsimile, or email.

3. The request for a suspensive administrative appeal shall state the basis and specific reasons for the appeal, and include any documentation that demonstrates that the determination was made in error.

4. If a timely request for a suspensive administrative appeal is received by the Office of the Secretary, the denial of license renewal application or license revocation shall be suspensive, and the outpatient abortion facility shall be allowed to continue to operate and provide abortions services until such time as the DAL, or its successor, issues a final administrative decision.

a. If the secretary determines that the deficiencies cited during any survey pose an imminent or immediate threat to the health, welfare, and safety of a patient, the denial of the license renewal application or license revocation may be immediate and may be enforced during the pendency of the administrative appeal. If the secretary makes such a determination, the outpatient abortion facility will be notified in writing.

5. Correction of a deficiency or deficiencies that is the basis for the denial of the initial license, denial of the license renewal application, or license revocation shall not be a basis for a suspensive administrative appeal.

6. If the final decision of the DAL, or its successor, is to reverse the denial of an initial license, the applicant's license will be granted upon the payment of any licensing fees, outstanding sanctions, or other fees due to the department. If the final decision of the DAL, or its successor, is to reverse the denial of a license renewal application or license revocation, the license will be reinstated upon the payment of any licensing fees, outstanding sanctions, or other fees due to the department.

7. If the final decision of the DAL, or its successor, is to affirm the denial of a license renewal application or license revocation, the outpatient abortion facility shall:

a. immediately cease and desist providing abortion services as an outpatient abortion facility;

b. provide written notice to all of the outpatient abortion facility's staff, including the medical director, and to any patient having an abortion procedure within the last 30 calendar days of operation;

c. return the outpatient abortion facility license to the department; and

d. notify the department in writing of the secure and confidential location where the patient medical records will be stored, including the name, physical address, and contact person, within 10 days of the rendering of the administrative appeal judgment.

F. Prohibition Following Loss of License. If a license is revoked or license renewal application is denied other than for cessation of business or non-operational status, or if the license is surrendered in lieu of an adverse action, any owner, officer, member, manager, director, or administrator of the outpatient abortion facility may be prohibited from owning, managing, directing, or operating another outpatient abortion facility in the state of Louisiana for two years.

G. If the department has issued a notice of license revocation or notice of immediate suspension of license at the time the license renewal application is submitted, the department shall deny the license renewal application. The

denial of the license renewal application does not affect, in any manner, the license revocation action.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4417. Immediate Suspension of License

A. Pursuant to R.S. 2175.6, the secretary may issue an immediate suspension of a license if any investigation or survey determines that the applicant or outpatient abortion facility is in violation of any provision of R.S. 40:2175 et seq., in violation of the rules promulgated by the department, or in violation of any other federal or state law or regulation, and not in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures, and the secretary determines that the violation or violations pose an imminent or immediate threat to the health, welfare, or safety of a client or patient.

B. Notice of Immediate Suspension of License. The secretary shall provide written notice of the immediate suspension of license.

C. Effective date. The suspension of the license is effective immediately upon the receipt of the written notice of immediate suspension of license.

D. Administrative Appeal. The outpatient abortion facility shall have the right to request a devolutive administrative appeal of the immediate suspension of license.

1. The request for a devolutive administrative appeal must be in writing and submitted to the DHH Office of the Secretary within 30 calendar days of receipt of the notice of immediate suspension of license.

2. The request for a devolutive administrative appeal shall specify in detail the reasons why the appeal is lodged.

E. Injunctive Relief. The outpatient abortion facility shall have the right to file for injunctive relief from the immediate suspension of license.

1. Venue. Any action for injunctive relief shall be filed with the district court for the parish of East Baton Rouge.

2. Burden of Proof. Before injunctive relief may be granted, the outpatient abortion facility shall prove by clear and convincing evidence that the secretary's decision to issue the immediate suspension of license was arbitrary and capricious.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

Subchapter B. Administration and Organization

§4421. Governing Body

A. The outpatient abortion facility shall have a governing body that assumes full responsibility for the total operation of the outpatient abortion facility.

1. The governing body shall consist of at least one individual who will assume full responsibility.

2. The outpatient abortion facility shall maintain documentation on the licensed premises identifying the following information for each member of the governing body:

- a. name;
- b. contact information;
- c. address; and
- d. terms of membership.

3. The governing body shall develop and adopt bylaws which address its duties and responsibilities.

4. The governing body shall, at minimum, meet annually and maintain minutes of such meetings documenting the discharge of its duties and responsibilities.

B. The governing body shall be responsible for:

1. ensuring the outpatient abortion facility's continued compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures;

2. designating a person to act as the administrator and delegating sufficient authority to this person to manage the day-to-day operations of the facility;

3. designating a person to act as the medical director and delegating authority to this person to allow him/her to direct the medical staff, nursing personnel, and medical services provided to each patient;

4. evaluating the administrator and medical director's performance annually, and maintaining documentation of such in their respective personnel files;

5. ensuring that upon hire and prior to providing care to patients and, at a minimum, annually, each employee is provided with orientation, training, and evaluation for competency according to their respective job descriptions;

6. developing, implementing, enforcing, monitoring, and annually reviewing in collaboration with the administrator, medical director, and registered nurse, written policies and procedures governing the following:

- a. the scope of medical services offered;
- b. personnel practices, including, but not limited to:
 - i. developing job descriptions for licensed and non-licensed personnel consistent with the applicable scope of practice as defined by federal and state law;
 - ii. developing a program for orientation, training, and evaluation for competency; and
 - iii. developing a program for health screening;
- c. the management of medical emergencies and the immediate transfer to a hospital of patients requiring emergency medical care beyond the capabilities of the outpatient abortion facility which shall identify emergency medical equipment and medications that will be used to provide for basic life support until emergency medical services arrive and assume care; and
- d. disaster plans for both internal and external occurrences;

7. approving all bylaws, rules, policies, and procedures formulated in accordance with all applicable state laws, rules, and regulations;

8. ensuring all bylaws, rules, policies, and procedures formulated in accordance with all applicable state laws, rules, and regulations are maintained on the licensed premises and readily accessible to all staff;

9. maintaining organization and administration of the outpatient abortion facility;

10. acting upon recommendations from the medical director relative to appointments of persons to the medical staff;

11. ensuring that the outpatient abortion facility is equipped and staffed to meet the needs of its patients;

12. ensuring services that are provided through a contract with an outside source are provided in a safe and effective manner;

13. ensuring that the outpatient abortion facility develops, implements, monitors, enforces, and reviews at a minimum, quarterly, a quality assurance and performance improvement (QAPI) program;

14. developing, implementing, monitoring, enforcing, and reviewing annually written policies and procedures relating to communication with the administrator, medical director, and medical staff to address problems, including, but not limited to, patient care, cost containment, and improved practices;

15. ensuring that the outpatient abortion facility conducts annual drills in accordance with the disaster plan and documents same;

16. ensuring that the outpatient abortion facility procures emergency medical equipment and medications that will be used to provide for basic life support until emergency medical services arrive and assume care; and

17. ensuring that the outpatient abortion facility orders and maintains a supply of emergency drugs for stabilizing and/or treating medical and surgical complications for intra-operative and post-operative care on the licensed premises, subject to the approval by the medical director.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4423. Staffing Requirements, Qualifications, and Responsibilities

A. General Provisions. An outpatient abortion facility shall have enough qualified personnel as indicated under this Chapter who are available to provide direct patient care as needed by all patients and administrative and nonclinical services needed to maintain the operation of the outpatient abortion facility in accordance with the provisions of this Chapter.

B. Administrator. The outpatient abortion facility shall have an administrator designated by the governing body who is responsible for the day-to-day management, supervision, and operation of the outpatient abortion facility. The administrator shall be an on-site employee who shall be employed on a full-time basis.

1. Qualifications. The administrator shall be at least 18 years of age and possess a high school diploma or equivalent.

2. The outpatient abortion facility shall designate a person to act in the administrator's absence, and shall ensure this person meets the qualifications of the administrator

pursuant to this Chapter. The outpatient abortion facility shall maintain documentation on the licensed premises identifying this person and evidence of their qualifications.

3. Duties and Responsibilities. The administrator shall be responsible for:

a. employing licensed and non-licensed qualified personnel to provide the medical and clinical care services to meet the needs of the patients being served;

b. ensuring that upon hire and prior to providing care to patients, each employee is provided with orientation, training, and evaluation for competency as provided in this Chapter;

c. ensuring that written policies and procedures for the management of medical emergencies and the immediate transfer to a hospital of patients requiring emergency medical care beyond the capabilities of the outpatient abortion facility are developed, implemented, monitored, enforced, and annually reviewed, and readily accessible to all staff;

d. ensuring that emergency medical equipment and medications that will be used to provide for basic life support until emergency medical services arrive and assume care are maintained in proper working order and are available for use on a day-to-day basis on the licensed premises;

e. ensuring that a licensed physician who has admitting privileges or has a written transfer agreement with another physician(s) who has admitting privileges at a local hospital within the same town or city to facilitate emergency care is on the licensed premises when a patient is scheduled to undergo an abortion procedure;

f. ensuring that disaster plans for both internal and external occurrences are developed, implemented, monitored, enforced, and annually reviewed and that annual drills are held in accordance with the disaster plan. The outpatient abortion facility shall maintain documentation on the licensed premises indicating the date, type of drill, participants, and materials;

g. ensuring that a licensed medical professional trained in CPR and trained in the use of emergency equipment is on the licensed premises at all times when abortion procedures are being performed;

h. ensuring that patient medical records are completely and accurately documented consistent with the provisions of this Chapter within 30 days from the abortion procedure; and

i. maintaining current credentialing and/or personnel files on each employee that shall include documentation of the following:

i. a completed employment application;

ii. job description;

iii. a copy of current health screening reports conducted in accordance with the outpatient abortion facility policies and procedures and in compliance with all applicable federal, state, and local statutes, laws, rules, regulations, and ordinances, including department rules, regulations, and fees, governing or relating to outpatient abortion facilities, abortion or termination procedures, reporting requirements, ultrasound requirements, informed consent requirements or any other matter related to abortion or abortion procedures;

iv. documentation that each employee has successfully completed orientation, training, and evaluation for competency related to each job skill as delineated in their respective job description;

v. documentation that all licensed nurses have successfully completed a basic life support course; and

vi. other pertinent information as required by the outpatient abortion facility's policies and procedures.

4. All credentialing and/or personnel files shall be current and maintained on the licensed premises at all times.

C. Medical Staff. The outpatient abortion facility shall provide medical and clinical services. The outpatient abortion facility shall employ qualified medical staff to meet the needs of the patients.

1. Qualifications. A medical staff member shall be a physician, as defined in this Chapter, who has completed, at a minimum, a residency rotation in obstetrics/gynecology.

2. Medical Director. The outpatient abortion facility shall have a medical director designated and approved by and accountable to the governing body who is responsible for all medical care provided to patients in the facility, and for the ethical and professional practices of the medical staff.

a. When an outpatient abortion facility has only one medical staff member, that individual shall serve as medical director.

b. The outpatient abortion facility shall designate a physician, as defined in this Chapter, to act in the medical director's absence. The outpatient abortion facility shall maintain documentation on the licensed premises identifying this physician and evidence of his/her qualifications.

c. Duties and Responsibilities. The medical director shall be responsible for:

i. developing, implementing, enforcing, monitoring, and annually reviewing written policies and procedures governing the medical and clinical services at the outpatient abortion facility, including, but not limited to:

(a). pre-operative procedures, intraoperative procedures, post-operative care and procedures, discharge, and follow-up care;

(b). laboratory services;

(c). infection control;

(d). pharmaceutical services, including, but not limited to, identifying the drugs dispensed and/or administered to patients on the licensed premises;

(e). anesthesia services;

(f). emergency medical services, including, but not limited to:

(i). identifying emergency medical equipment and medications that will be used to provide for basic life support until emergency medical services arrive and assume care; and

(ii). identifying and ensuring that a supply of emergency drugs for stabilizing and/or treating medical and surgical complications are maintained on the licensed premises;

(g). patient medical records and reporting requirements;

(h). the examination of fetal tissue;

(i). the disposition of medical waste;

(j). physical environment; and

(k). quality assurance and performance improvement (QAPI) program;

ii. developing, implementing, enforcing, monitoring, annually reviewing written bylaws, rules, policies, and procedures for self-governing of the professional activity of all medical staff members including, but not be limited to:

(a). the structure of the medical staff;

(b). review of the credentials, and training, and competency of each medical staff member to perform medical and clinical services, at least every two years, and to delineate and to recommend approval for individual privileges;

(i). when an outpatient abortion facility employs one physician, the review shall be conducted by a peer physician, at least every two years, according to the provisions of this Section;

(ii). the recommendation shall be in writing and maintained on the licensed premises in the credentialing file;

(iii). verification that each member of the medical staff is a doctor who possesses a current license to practice medicine in Louisiana, is in good standing with the Louisiana State Board of Medical Examiners, and whose license does not restrict the doctor from performing the services at the outpatient abortion facility;

(iv). evaluation for competency and past performance of each medical staff member, at a minimum, annually, which shall include monitoring and evaluation of patient care provided;

(v). medical staff discipline; and

(vi). grievance process;

iii. monitoring and reviewing, at a minimum, quarterly, in collaboration with the QAPI team/committee, the medical and clinical services provided by the outpatient abortion facility to ensure acceptable levels of quality of care and services;

iv. reviewing reports of all accidents or unusual incidents occurring on the licensed premises and reporting to the administrator potential health and safety hazards;

v. ensuring that each patient receiving medical and clinical services is under the professional care of a member of the medical staff who shall assess, supervise, and evaluate the care of the patient;

vi. ensuring that a member of the medical staff remains on the licensed premises until each patient is assessed to be awake, alert, and medically stable prior to discharge; and

vii. ensuring that a member of the medical staff shall be either present or immediately available by telecommunications to the staff when there is a patient on the licensed premises.

D. Nursing Staff. The outpatient abortion facility shall provide nursing services. The outpatient abortion facility shall employ qualified nursing staff to meet the needs of the patients.

1. Registered Nurse. The outpatient abortion facility shall have a registered nurse (RN) who is responsible for the overall direction of all nursing staff and nursing services provided.

a. Qualifications. The RN shall:

i. have a current, unrestricted Louisiana registered nurse license; and

ii. be in good standing with the Louisiana State Board of Nursing.

2. Duties and Responsibilities. The RN shall be responsible for:

a. developing, implementing, enforcing, monitoring, and annually reviewing written policies and procedures governing the following:

i. personnel, including, but not limited to:

(a). developing a job description that delineates responsibilities and duties for each category of licensed and non-licensed nursing staff consistent with acceptable nursing standards of practice;

(b). orientation;

(c). training; and

(d). evaluation for competency;

ii. nursing care and services consistent with accepted nursing standards of practice;

b. assigning duties and functions to each licensed and non-licensed employee commensurate with his/her licensure, certification, experience, and competence consistent with acceptable nursing standards of practice;

c. verifying that each licensed nurse possesses a current and unrestricted license to practice nursing in Louisiana and is in good standing with the Louisiana State Board of Nursing;

d. ensuring that the number of nursing staff on duty is sufficient to meet the needs of the patient(s);

e. ensuring that at least one licensed nurse is present when there is a patient receiving or recovering from an abortion procedure on the licensed premises;

f. ensuring that each licensed nurse working at the outpatient abortion facility has successfully completed a basic life support course; and

g. developing, implementing, enforcing, monitoring, and reviewing annually in collaboration with the medical director, written policies and procedures establishing a formalized program of in-service training and evaluation for competency for each category of licensed and non-licensed nursing staff and for all nursing care and services provided at the outpatient abortion facility.

i. The RN shall ensure that the training is related to each job skill as delineated in their respective job description.

ii. The RN shall ensure an evaluation for competency is performed for each category of licensed and non-licensed nursing staff and for all nursing care and services provided.

iii. The RN shall maintain documentation in the personnel file of each nursing staff member evidencing the content of the training that was provided, including the name of the teacher, date, nurse's name, and documents provided.

iv. The RN shall maintain documentation in the personnel file of each nursing staff member evidencing that an evaluation for competency was conducted, including the name of the evaluator, date, nurse's name, and a notation that the nurse is competent in each job skill as delineated in their respective job description.

E. Orientation and Training. The administrator shall develop, implement, enforce, monitor, and annually review, in collaboration with the medical director and registered nurse, written policies and procedures regarding orientation and training of all employees.

1. Orientation. Upon hire and prior to providing care to patients, all employees shall be provided orientation related to the outpatient abortion facility's written policies and procedures governing the following:

- a. organizational structure;
- b. confidentiality;
- c. grievance process;
- d. disaster plan for internal and external occurrences;
- e. emergency medical services;
- f. program philosophy;
- g. personnel practices;
- h. reporting requirements; and
- i. basic skills required to meet the health needs and problems of the patients.

2. Training. Upon hire, and at a minimum, annually, all employees shall be provided training in each job skill as delineated in their respective job description.

a. Medical training of a licensed medical professional shall only be provided by a medical professional with an equivalent or higher license.

b. Training of a non-licensed employee related to the performance of job skills related to medical and clinical services shall only be provided by a licensed medical professional consistent with the applicable standards of practice.

c. All training programs and materials used shall be available for review by HSS.

d. The administrator shall maintain documentation of all of the training provided in each employee's personnel files.

F. Evaluation for Competency. Upon hire, and at a minimum, annually, the outpatient abortion facility shall conduct an evaluation for competency of all employees related to each job skill as delineated in their respective job description.

1. The evaluation for competency shall include the observation of job skills and return demonstration by the employee.

2. Evaluation for competency of a licensed medical professional shall only be provided by a medical professional with an equivalent or higher license.

3. Evaluation for competency of a non-licensed employee related to the performance of job skills related to medical and clinical services shall only be provided by a licensed medical professional consistent with the applicable scope of practice.

4. The administrator shall maintain documentation of all evaluations for competencies in each employee's personnel file.

G. Health Screening. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review written policies and procedures governing health screening of personnel in accordance with all applicable federal, state, and local statutes, laws, ordinances, and department rules and regulations. The administrator shall

maintain documentation of health screening reports in each employee's personnel file.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4425. Patient Medical Records and Reporting Requirements

A. General Provisions

1. The outpatient abortion facility shall establish and maintain a patient medical record on each patient.

2. The patient medical record shall be:

- a. completely and accurately documented; and
- b. readily available and systematically organized to facilitate the compilation and retrieval of information.

3. The outpatient abortion facility shall ensure the confidentiality of patient medical records, including information in a computerized medical record system, in accordance with the Health Insurance Portability and Accountability Act (HIPAA) regulations.

4. Safeguards shall be established to protect the patient medical records from loss or damage.

B. Retention of Patient Medical Records. Patient medical records shall be retained by the outpatient abortion facility for a period of not less than seven years from the date of discharge. If the woman is a minor, then the medical record of the minor shall be kept for at least seven years or for five years after the minor reaches the age of majority, whichever is greater. Patient medical records shall be maintained on the premises for at least one year and shall not be removed except under court orders or subpoenas. Any patient medical record maintained off-site after the first year shall be provided to the department for review no later than 24 hours from the time of the department's request.

C. Contents of Patient Medical Record

1. The following minimum data shall be kept on all patients:

- a. identification data;
- b. date of procedure;
- c. medical and social history;
- d. anesthesia and surgical history;
- e. physical examination notes;
- f. chief complaint or diagnosis;
- g. clinical laboratory reports;
- h. pathology reports;
- i. individualized physician's orders;
- j. radiological/ultrasound reports;
- k. consultation reports (when appropriate);
- l. medical and surgical treatment;
- m. progress notes, discharge notes, and discharge summary;
- n. nurses' notes, including, but not limited to, all pertinent observations, treatments, and medications dispensed and/or administered;
- o. medication administration records, including, but not limited to, the date, time, medication, dose, and route;
- p. patient medical records shall contain documentation of any and all prescription drugs dispensed to each patient, including, but not limited to the:
 - i. full name of the patient;
 - ii. name of the prescribing physician;

- iii. name and strength of the drug;
- iv. quantity dispensed; and
- v. date of issue;
- q. signed and dated authorizations, consents, releases, or notices required by all applicable federal, state, and local statutes, laws, ordinances, and department rules and regulations;
- r. operative report;
- s. anesthesia report, including, but not limited to, the date, time, type of anesthesia, dose, and route; and
- t. special procedures reports.

2. Each entry documented in the patient's medical record shall be signed by the physician as appropriate, i.e., attending physician, consulting physician, anesthesiologist, pathologist, etc. Nursing notes and observations shall be signed by the nurse. All entries shall be in writing and contain the date, time, and signature of the individual(s) delivering the patient care and services.

D. Nothing in this Section is intended to preclude the use of automated or centralized computer systems or any other techniques for the storing of medical records, provided the regulations stated herein are met.

E. Other Reports. The outpatient abortion facility shall maintain a daily patient roster of all patients receiving abortion services. This daily patient roster shall be retained for a period of three years.

F. Reporting Requirements

1. The outpatient abortion facility shall maintain documentation to support that the outpatient abortion facility is compliant with all reporting requirements, including, but not limited to, the induced termination of pregnancy (ITOP) form, and other documentation as required by federal, state, and local statutes, laws, ordinances, and department rules and regulations.

2. The outpatient abortion facility shall report in accordance with all applicable state laws for the reporting of crimes against a child that include but are not limited to:

- a. rape;
- b. sexual battery;
- c. incest; and
- d. carnal knowledge of a juvenile.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4427. Quality Assurance and Performance Improvement Program (QAPI)

A. The outpatient abortion facility shall develop, implement, enforce, maintain, and annually review a written QAPI program subject to approval by the governing body, which puts systems in place to effectively identify issues for which quality monitoring and performance improvement activities are necessary. The QAPI program shall include plans of action to correct identified issues including, but not limited to, monitoring the effect of implemented changes and making necessary revisions to the plan of action.

1. Plans of Action. The outpatient abortion facility shall develop and implement a QAPI plan of action designed to effectively identify issues for which quality monitoring and performance improvement activities are necessary.

2. The QAPI plan of action shall include the following:

- a. processes for receiving input regarding the quality of medical and clinical services received;
- b. patient medical records that are complete and current;
- c. processes for identifying on a quarterly basis the risk factors that affect or may affect the health and safety of the patients of the outpatient abortion facility receiving medical and clinical services. Examples include, but are not limited to:
 - i. review and resolution of patient grievances; and
 - ii. review and resolution of patient/employee incidents involving medication errors and equipment failure;
- d. a process to review and develop action plans to resolve all system wide issues identified as a result of the processes above.

3. The QAPI outcomes shall be documented and reported to the administrator in writing for action, as necessary, for any identified systemic problems.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

Subchapter C. Pre-operative, Intra-operative, and Post-Operative Procedures

§4431. Screening and Pre-Operative Services

A. Verification of Pregnancy. The presence of an intrauterine pregnancy shall be verified by one of the following:

- 1. urine or serum pregnancy test performed on-site;
- 2. detection of fetal heart tones; or
- 3. ultrasonography.

B. Gestational age shall be estimated by the following methods pre-operatively:

- 1. first date of last menstrual period, if known;
- 2. pelvic examination; or
- 3. ultrasonography.

C. Laboratory Tests

1. The laboratory tests listed below shall be performed at least 30 days prior to the abortion procedure:

- a. hematocrit or hemoglobin determination; and
- b. Rh factor status.

2. The results of the laboratory tests shall be documented in the patient's medical record at least 24 hours prior to the abortion procedure.

3. The physician performing the abortion shall document acknowledgement of the results of the laboratory tests in the patient's medical record prior to the abortion procedure.

D. Minors

1. No physician shall perform or induce an abortion upon any pregnant woman who is under the age of 18 years and who is not emancipated judicially or by marriage unless the physician has received the following documents:

- a. a notarized statement, pursuant to R.S. 40:1299.35.5, signed by the mother, father, legal guardian, or tutor of the minor declaring that the affiant has been informed that the minor intends to seek an abortion and that the affiant consents to the abortion; or

b. a court order pursuant to R.S. 40:1299.35.5; and
c. a signed, dated, and timed document by the attending physician and/or licensed nurse, shall be obtained before the administration of any type of anesthesia which indicates if any person has or has not compelled the female child to undergo an abortion against her will.

2. All documentation related to consent and coercion shall be maintained in the medical record.

E. Ultrasound Requirements. Except in the case of a medical emergency, and in addition to the provisions of R.S. 40:1299.35.6, consent to an abortion of an unborn child at any stage of gestational development is voluntary and informed only if an obstetric ultrasound is performed in accordance with the provisions of this Section.

1. Qualifications to Perform Ultrasound. The ultrasound shall be performed by the physician who is to perform the abortion or a qualified person who is the physician's agent. For purposes of this Section, *qualified person* means a person having documented evidence that he or she has completed a course in the operation of ultrasound equipment and is in compliance with any other requirements of law regarding the operation of ultrasound equipment.

2. Requirements. At least 24 hours prior to the pregnant woman having any part of an abortion performed or induced, and prior to the administration of any anesthesia or medication in preparation for the abortion on the pregnant woman, the physician who is to perform the abortion or a qualified person who is the physician's agent shall comply with all of the following requirements:

a. perform an obstetric ultrasound on the pregnant woman, offer to simultaneously display the screen which depicts the active ultrasound images so that the pregnant woman may view them and make audible the fetal heartbeat, if present, in a quality consistent with current medical practice. Nothing in this Section shall be construed to prevent the pregnant woman from not listening to the sounds detected by the fetal heart monitor, or from not viewing the images displayed on the ultrasound screen;

b. provide a simultaneous and objectively accurate oral explanation of what the ultrasound is depicting, in a manner understandable to a layperson, which shall include the presence and location of the unborn child within the uterus and the number of unborn children depicted, the dimensions of the unborn child, and the presence of cardiac activity if present and viewable, along with the opportunity for the pregnant woman to ask questions;

c. offer the pregnant woman the option of requesting an ultrasound photograph or print of her unborn child of a quality consistent with current standard medical practice that accurately portrays, to the extent feasible, the body of the unborn child including limbs, if present and viewable;

d. from a form that shall be produced and made available by the department, staff will orally read the statement on the form to the pregnant woman in the ultrasound examination room prior to beginning the ultrasound examination, and obtain from the pregnant woman a copy of a completed, signed, and dated form;

e. retain copies of the election form and certification prescribed above. The certification shall be placed in the medical file of the woman and shall be kept by

the outpatient abortion facility for a period of not less than seven years. If the woman is a minor, the certification shall be placed in the medical file of the minor and kept for at least seven years or for five years after the minor reaches the age of majority, whichever is greater. The woman's medical files shall be kept confidential as provided by law.

3. Options to view or listen to required medical information shall be in accordance with the provisions of R.S. 40:1299.35.6.

a. A pregnant woman may choose not to exercise her option to request an ultrasound photograph print.

b. A pregnant woman may choose not to view the ultrasound images required to be provided to and reviewed with the pregnant woman.

c. A pregnant woman may choose not to listen to the sounds detected by the fetal heart monitor required to be provided to the pregnant woman.

F. Medical Emergencies. Upon a determination by a physician that a medical emergency, as defined pursuant to R.S. 40:1299.35.6 exists with respect to a pregnant woman, the outpatient abortion facility shall certify in writing the specific medical conditions that constitute the emergency. The certification shall be placed in the medical file of the woman.

G. Information and Informed Consent Pursuant to R.S. 40:1299.35.6

1. Oral and Written Information Provided by Physician or Referring Physician

a. At least 24 hours before the abortion the physician who is to perform the abortion or the referring physician shall provide informed consent to the pregnant woman seeking an abortion. The informed consent shall be communicated both orally and in person, and in writing, and shall be provided in a private room.

b. Documentation. The documentation of all such informed consent provided shall be maintained in the patient's medical record.

c. The informed consent shall also contain language explaining the following information to the pregnant woman seeking an abortion:

i. the option of reviewing and receiving an oral explanation of an obstetric ultrasound image of the unborn child;

ii. that the pregnant woman shall not be required to view or receive an explanation of the obstetric ultrasound images;

iii. that the pregnant woman shall not be penalized if she chooses not to view or receive an explanation of the obstetric ultrasound images;

iv. that the physician shall not be penalized if the pregnant woman chooses not to view or receive an explanation of the obstetric ultrasound images; and

v. inclusion in the patient's printed materials of a comprehensive list, compiled by the department, of facilities that offer obstetric ultrasounds free of charge.

2. Oral Information from a Physician or Qualified Person

a. When an initial contact is made by a person seeking to schedule an abortion for herself, a minor, or other adult woman, regardless of the means of contact, the physician who is to perform the abortion or any qualified

person acting on behalf of the physician shall inform the person of the internet address of the department's abortion alternatives and informed consent website.

3. Oral Information Provided by Physician, Referring Physician, or Qualified Person

a. At least 24 hours before a scheduled abortion the physician who is to perform the abortion, the referring physician, or a qualified person shall inform the pregnant woman seeking an abortion, orally and in-person that:

i. medical assistance may be available for prenatal care, childbirth, and neonatal care and that more detailed information on the availability of such assistance is contained on the department's website and printed materials;

ii. a pamphlet is available that describes the unborn child and contains a directory of agencies that offer an abortion alternative;

iii. the father of the unborn child is liable to assist in the support of the child, even if he has offered to pay for the abortion. In the case of rape this information may be omitted;

iv. the pregnant woman seeking an abortion is free to withhold or withdraw consent to the abortion at any time before or during the abortion without affecting her right to future care or treatment and without loss of any state or federally funded benefits to which she might otherwise be entitled.

4. Provision of Printed Materials

a. At least 24 hours before the abortion, the pregnant woman seeking an abortion shall be given a copy of the printed materials pursuant to R.S. 40:1299.35.6 by the physician who is to perform the abortion, the referring physician, or a qualified person.

b. If the pregnant woman seeking an abortion is unable to read the materials, the material shall be read to her.

c. If the pregnant woman seeking an abortion asks questions concerning any of the information or materials, answers shall be provided to her in her own language.

5. Certification and Reporting

a. Prior to the abortion, the outpatient abortion facility shall ensure the pregnant woman seeking an abortion has certified, in writing on a form provided by the department that the information and materials required were provided at least 24 hours prior to the abortion. This form shall be maintained in the woman's medical record.

b. Prior to performing the abortion, the physician who is to perform the abortion or his agent receives a copy of the written certification.

c. The pregnant woman seeking an abortion is not required to pay any amount for the abortion procedures until the 24 hour period has expired.

6. Medical Emergency. Where a medical emergency, as defined pursuant to R.S. 40:1299.35.6 compels the performance of an abortion, the physician shall orally inform the woman, before the abortion, if possible, of the medical indications supporting his judgment that an abortion is necessary to avert her death or to avert substantial and irreversible impairment of a major bodily function.

7. Reporting Requirements. Any physician who has provided the information and materials to any woman in

accordance with the requirements of this Section shall provide to the department:

a. with respect to a woman upon whom an abortion is performed, all information as required by R.S. 40:1299.35.10 as well as the date upon which the information and materials required to be provided under this Section were provided, as well as an executed copy of the certification form. This form shall be maintained in the woman's medical record;

b. with respect to any woman to whom the printed and oral information and materials have been provided pursuant to R.S. 40:1299.35.6, but upon whom the physician has not performed an abortion, the name and address of the facility where the required information was provided and if executed by the woman, a copy of the certification form required. This form shall be maintained in the woman's medical record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4433. Drug or Chemical Induced Abortion

A. When any drug or chemical is used for the purpose of inducing an abortion as defined in R.S. 40:1299.35.2.1, the physician who prescribed the drug or chemical shall be in the same room and in the physical presence of the pregnant woman when the drug or chemical is initially administered, dispensed, or otherwise provided to the pregnant woman.

B. Documentation shall be recorded as to the date, time, method and name and signature of the physician who initially administered, dispensed, or otherwise provided the drug or chemical to the pregnant woman. This documentation shall be maintained in the patient's medical record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4435. Intra-operative Procedures

A. The outpatient abortion facility shall ensure that emergency medical equipment and supplies as required by the governing body, medical director and medical staff are available for intra-operative care and shall include, but not limited to:

1. surgical or gynecologic table;
2. surgical instrumentation;
3. emergency drugs for stabilizing and/or treating medical and surgical complications as approved by the medical director;
4. oxygen;
5. intravenous fluids; and
6. sterile dressing supplies.

B. The physician performing the abortion shall be present on the licensed premises prior to the administration of any type of anesthesia.

C. The outpatient abortion facility shall ensure that the medical equipment required for an abortion shall be maintained and immediately available to the physician in the procedure and/or recovery room(s) to provide emergency medical care and services.

D. During the abortion procedure, the patient shall be assessed and monitored by a licensed nurse for the following: level of consciousness, respiratory status, cardiovascular status, and any potential sequelae related to the abortion procedure. The results of this assessment shall be documented in the patient's medical record.

E. Immediately following the abortion procedure, the patient shall be assessed and monitored by a licensed nurse for the following: level of consciousness, respiratory status, cardio-vascular status, and any potential sequelae related to the abortion procedure. The results of this assessment shall be documented in the patient's medical record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4437. Post-Operative Care, Procedures, and Discharge

A. Post-Operative Care and Procedures

1. The outpatient abortion facility shall have immediately available a supply of emergency drugs for stabilizing and/or treating medical and surgical complications for post-operative care on the licensed premises.

2. The patient's recovery shall be supervised by a licensed physician or a licensed nurse trained in post-operative care.

3. If general anesthesia is administered during the abortion procedure, the outpatient abortion facility shall have licensed nursing personnel trained in post-anesthesia care.

4. Upon completion of an abortion procedure, the physician shall immediately perform a gross examination of the uterine contents and shall document the findings in the patient's medical record. If no products of conception are visible, the physician shall assess the patient for risk of complications of an incomplete abortion or ectopic pregnancy.

5. Upon admission to the recovery room, the patient shall be assessed for the following, including, but not limited to: level of consciousness, respiratory status, cardio-vascular status, pain level, bleeding, and any potential sequelae related to the abortion procedure. The results of this assessment shall be documented in the patient's medical record.

6. A patient shall not be left unattended in the recovery room.

7. Rh immunoglobulin administration shall be offered to Rh-negative women and documented in the patient's medical record. If Rh immunoglobulin is not administered in the facility, one of the following is required:

a. informed waiver signed by a patient who refuses RH immunoglobulin; or

b. documentation of other arrangements for administration of RH immunoglobulin.

B. Discharge Procedures

1. The patient shall be given verbal and written post-operative instructions for follow-up care. A contact telephone number for post-operative care/services from the facility shall be available to the patient on a 24-hour basis.

2. A member of the medical staff shall remain on the licensed premises until each patient is assessed to be awake, alert, and medically stable prior to discharge.

3. A copy of the discharge instructions signed by the patient and the physician shall be maintained in the patient's medical record.

4. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review written policies and procedures to ensure that products of conception are disposed of in compliance with Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), and with any other applicable federal, state, and local statutes, laws, ordinances, and department rules and regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4439. Anesthesia Services

A. Subject to the approval of the medical director, the outpatient abortion facility shall develop, implement, monitor, enforce, and annually review written policies and procedures governing the preparation of and administration of drugs relating to the types of anesthesia administered during the abortion procedure. The outpatient abortion facility shall provide training and evaluation for competency of the types of anesthesia administered during the abortion procedure.

B. Qualifications to Administer Anesthesia. Local anesthesia, nitrous oxide, intramuscular, oral, and intravenous sedation shall be administered by the physician performing the abortion or by licensed nursing staff who have been deemed competent to administer sedation under the orders and supervision of the physician or pursuant to their scope of practice as defined under the Nurse Practice Act.

C. The physician performing the abortion shall be present on the licensed premises prior to the administration of all types of anesthesia.

D. General anesthesia, if used, shall be administered by an anesthesiologist or certified registered nurse-anesthetist (CRNA) who is under the supervision of the physician performing the abortion.

E. When there is a general anesthesia patient present on the licensed premises, personnel trained in the use of all emergency equipment required shall be present on the premises.

F. A physician shall be present on the licensed premises during the post-anesthesia recovery period until the patient is fully reacted and stable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

Subchapter D. Physical Environment

§4445. General Requirements

A. General Provisions

1. The outpatient abortion facility shall be designed, constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public at all times.

2. All openings to the outside shall be maintained to protect against the entrance of insects and animals.

3. An area for at least one stretcher and one wheelchair shall be provided. The area shall not encroach upon any required egress path or other required clear dimension.

4. Flooring in all patient areas shall be readily cleanable, monolithic and joint free, and slip-resistant in accordance with the American Society for Testing and Materials (ASTM), C1028-07e1.

5. Wall finishes in all patient areas shall be smooth, moisture resistant, washable, and free of fissures, open joints, or crevices that may retain or permit passage of dirt particles.

6. Wall bases in all patient areas shall be monolithic and coved with the floor, tightly sealed to the wall, and constructed without voids.

7. A separate waiting area shall be provided that is sufficient in size to provide seating space for patients, staff, and visitors of the patient.

8. Toilet facilities for patients, staff, and visitors shall be installed and maintained in accordance with the requirements of Part XIV (Plumbing) and Part XVII (Public Buildings, Schools, and Other Institutions) of the Louisiana state Sanitary Code (LAC 51:XIV and XVII, respectively).

a. Every toilet room shall contain at least one water closet and one lavatory. Such toilet facilities shall be provided with ventilation in accordance with the requirements of LAC 51:XIV and XVII.

b. Hot and cold water delivered through a mixing faucet, soap, and mechanical hand drying devices and/or disposable paper towels shall be provided at all hand washing lavatories/stations.

c. Showers or shower/tub combinations, if provided, shall meet the requirements of LAC 51:XIV.

B. Signage. The outpatient abortion facility shall provide:

1. an exterior sign that can be viewed by the public. The sign shall contain, at a minimum, the "DBA" name of the facility as it appears on the outpatient abortion facility license issued by the department;

2. clearly identifiable and distinguishable signs for outpatient abortion facilities operating within another facility which shall comply with the provisions of R.S. 40:2007.

C. Procedure Room

1. Abortions shall be performed in a segregated procedure room, removed from general traffic lines with a minimum clear floor area of 360 square feet with a minimum clear dimension of 18 feet.

2. There shall be a hand washing station with hands-free or wrist blade-operable controls within each procedure room and within each recovery room. Fixtures shall not encroach upon any required egress path or other required clear dimension.

D. Recovery Area

1. The outpatient abortion facility shall have a separate recovery room or area with a minimum clear floor area of 80 square feet with a minimum of 4 feet between patient stretchers or beds and adjacent walls (at the stretcher's sides and foot), and at least 3 feet from the foot of the stretcher or bed to the closed cubicle curtain.

2. The outpatient abortion facility shall have a nurse's station equipped with a countertop, space for supplies, provisions for charting, and a communication system. The nursing station shall be arranged to provide for direct visual observation of all traffic into the recovery area.

E. Equipment and Supply Storage Areas. The outpatient abortion facility shall have:

1. a soiled utility room which contains a flushing-rim clinical sink or equivalent flushing-rim sink, a work counter, a hand washing station, waste receptacle(s), and a space for soiled linen;

2. a clean utility room which is used for clean or sterile supplies;

3. an equipment and supply storage room with minimum 70 square feet of floor space shall be provided for equipment and supplies used in the procedure room;

4. a designated separate space shall be provided for soiled materials storage. Soiled materials shall not be stored or transported through the clean laundry area.

F. If the outpatient abortion facility maintains an in-house laundry, the areas shall be designed in accordance with acceptable hospital laundry design.

G. Signage in Abortion Facilities. The outpatient abortion facility shall ensure a sign is obtained from the department in accordance with the Forced Abortion Prevention Sign Act.

1. Display. The sign shall be posted on the licensed premises and shall be clearly visible to patients. The sign provided shall be conspicuously posted in each patient admission area, waiting room, and patient consultation room used by patients on whom abortions are performed, induced, prescribed for, or who are provided with the means for an abortion.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4447. Infection Control

A. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review its written infection control program. The purpose of this program shall seek to minimize infections and communicable diseases through prevention, investigation, and reporting of infections. This program shall include all contracted services.

B. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review, with the approval of the medical director, written policies and procedures for preventing, identifying, reporting, investigating, controlling, and immediately implementing corrective actions relative to infections and communicable diseases of patients and personnel. At a minimum, the policies shall address:

1. alcohol based hand rub and hand hygiene;
2. use of all types of gloves;
3. decontamination of equipment between each patient use, including, but not limited to, chairs and procedure room tables;
4. linen cleaning, if applicable;
5. waste management;
6. environmental cleaning;
7. reporting, investigating, and monitoring of surgical infections;
8. sterilization procedures and processes, if applicable;
9. single use devices;

10. disinfecting procedures and processes; and
11. breaches of infection control practices.

C. Supplies shall not be reused if labeled for single use.

D. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review written policies and procedures which require immediate reporting, according to the latest criteria established by the Centers for Disease Control (CDC), Office of Public Health (OPH) and the Occupational Safety and Health Administration (OSHA), of the suspected or confirmed diagnosis of a communicable disease.

E. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review a written waste management program that identifies and controls wastes and hazardous materials to prevent contamination and spread of infection within the facility. The program shall comply with all applicable laws and regulations governing wastes and hazardous materials and the safe handling of these materials.

F. There shall be a separate sink for cleaning instruments and disposal of liquid waste.

G. The outpatient abortion facility shall develop, implement, and enforce/maintain written policies and procedures to ensure items are contained and handled during the sterilization process to assure sterility is not compromised prior to use.

H. After sterilization, instruments shall be stored in a designated clean area so that sterility is not compromised.

I. Sterile packages are inspected for integrity and compromised packages shall be reprocessed before use.

J. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review written policies and procedures governing the following:

1. the handling, processing, storing, and transporting of clean and dirty laundry;
2. special cleaning and decontamination processes are employed for contaminated linens, if an in-house laundry is maintained on the licensed premises; and
3. housekeeping services maintain a safe and clean environment.

K. Housekeeping supplies shall be provided to adequately maintain the licensed premises.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4449. Laboratory Services

A. The outpatient abortion facility shall have laboratory services available to meet the needs of its patients.

B. The outpatient abortion facility shall maintain a clinical laboratory improvement amendment (CLIA) certificate for the laboratory services provided on the licensed premises.

C. The outpatient abortion facility shall ensure that all contracted laboratory services are provided by a CLIA certified laboratory.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

§4451. Pharmaceutical Services

A. All outpatient abortion facilities shall have a controlled dangerous substance (CDS) license issued by the Louisiana Board of Pharmacy and a Drug Enforcement Agency (DEA) registration.

B. The outpatient abortion facility shall develop, implement, enforce, monitor, and annually review written policies and procedures that govern the safe storage, prescribing, dispensing, preparing and administering of drugs and biologicals on the licensed premises.

C. Storage Areas. The outpatient abortion facility shall provide a designated secure storage area for storing drugs and biologicals.

1. The designated storage area shall be constructed and maintained to prevent unauthorized access.

2. The designated storage area shall adhere to the manufacturer's suggested recommendations for storage of drugs.

3. Locked areas that are used to store medications including controlled substances, shall conform to all applicable federal and state laws, and the outpatient abortion facility's policies and procedures.

D. The outpatient abortion facility shall maintain written records documenting the ordering, receiving, dispensing, administering, and disposing of unused drugs.

E. The outpatient abortion facility shall maintain written documentation of all drugs prescribed and/or dispensed to each patient, including, but not limited to the:

1. full name of the patient;
2. name of the prescribing and/or dispensing physician;
3. name and strength of the drug;
4. quantity prescribed and/or dispensed; and
5. date of issue.

F. Preparation and Administration of Drugs. The outpatient abortion facility shall develop, implement, enforce, monitor, and review annually written policies and procedures governing the preparation of drugs and biologicals.

1. The outpatient abortion facility shall ensure that all drugs and biologicals are prepared and administered pursuant to an order from an individual who has prescriptive authority under the laws of Louisiana. Each order shall be in writing, patient specific, dated, timed, and signed by an individual with prescriptive authority under the laws of Louisiana. A copy of such orders shall be maintained in each, individual patient medical record.

G. The outpatient abortion facility shall order and maintain a supply of emergency drugs for stabilizing and/or treating medical and surgical complications on the licensed premises as authorized by the medical director.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2175.1 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:

Interested persons may submit written comments to J. Ruth Kennedy, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. She is responsible for responding to inquiries regarding this

Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Kathy H. Kliebert
Secretary

1311#057

DECLARATION OF EMERGENCY

Department of Health and Hospitals Bureau of Health Services Financing

Adult Dentures Program Reimbursement Rate Reduction (LAC 50:XXV.701)

The Department of Health and Hospitals, Bureau of Health Services Financing amends LAC 50:XXV.701 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act and as directed by Act 14 of the 2013 Regular Session of the Louisiana Legislature which states: "The secretary is directed to utilize various cost containment measures to ensure expenditures remain at the level appropriated in this Schedule, including but not limited to precertification, preadmission screening, diversion, fraud control, utilization review and management, prior authorization, service limitations, drug therapy management, disease management, cost sharing, and other measures as permitted under federal law." This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R. S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

Due to a budgetary shortfall in state fiscal year 2013, the Department of Health and Hospitals, Bureau of Health Services Financing amended the provisions governing the reimbursement methodology for adult denture services to reduce the reimbursement rates (*Louisiana Register*, Volume 39, Number 2).

Due to a budgetary shortfall in state fiscal year 2014, the department promulgated an Emergency Rule which amended the provisions governing the reimbursement methodology for adult denture services to reduce the reimbursement rates (*Louisiana Register*, Volume 39, Number 8). This Emergency Rule is being promulgated to continue the provisions of the August 1, 2013 Emergency Rule. This action is being taken to avoid a budget deficit in the medical assistance programs.

Effective November 30, 2013, the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions governing the reimbursement methodology for adult denture services to reduce the reimbursement rates.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part XXV. Adult Dentures

Chapter 7. Reimbursement

§701. Fees

A. - C. ...

D. Effective for dates of service on or after August 1, 2013, the reimbursement for adult denture services shall be reduced by 1.5 percent of the fee amounts on file as of July 31, 2013.

1. Removable prosthodontics shall be excluded from the August 1, 2013 reimbursement rate reduction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 31:81 (January 2005), repromulgated LR 31:1589 (July 2005), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 39:316 (February 2013), LR 39:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to J. Ruth Kennedy, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. She is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Kathy H. Kliebert
Secretary

1311#061

DECLARATION OF EMERGENCY

Department of Health and Hospitals Bureau of Health Services Financing and Office of Behavioral Health

Behavioral Health Services Physician Payment Methodology (LAC 50:XXXIII.Chapter 17)

The Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Behavioral Health adopt LAC 50:XXXIII.Chapter 17 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Bureau of Health Services Financing adopted provisions to implement a coordinated behavioral health services system under the Medicaid Program, called the Louisiana Behavioral Health Partnership (LBHP), to provide adequate coordination and delivery of behavioral health services through the utilization of a Statewide Management Organization (*Louisiana Register*, Volume 38, Number 2).

The Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Behavioral Health promulgated an Emergency Rule which amended the provisions governing the reimbursement of physician services rendered in the LBHP in order to establish a distinct payment methodology that is independent of the payment methodology established for physicians in the Professional Services Program (*Louisiana Register*, Volume 39, Number